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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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George Gullickson

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EXAMINER

HUPCZEY, JR, RONALD JAMES

ART UNIT

PAPER NUMBER

3739

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/697,486	Applicant(s) GULLICKSON ET AL.	
	Examiner RONALD J. HUPCZEY, JR.	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments and arguments, received on June 18th, 2008, have been fully considered by the examiner. Claims 1-29 are currently pending with claims 28 and 29 newly added. The following is a complete response to the June 18th, 2008 communication.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 27 recites the limitation "the arcuate opening" in page 8, line 19. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

6. Claims 1-9 and 14-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardeo et al (US Pat. No. 6,530,897 B2) in view of Mercereau et al (US Pat. No. 6,676,668 B2).

Regarding claims 1, 2, 22, 23, 28 and 29, Nardeo discloses a steerable catheter containing an elongated catheter body (catheter tubing **100**) including a proximal end, a distal segment (see figure 1) and a deflection lumen extending from the proximal end toward the distal segment (parallel lumen **15**, see figures 1 and 2) extending from the proximal end to the distal segment. Nardeo further discloses a handle (control handle **200**) coupled to the catheter body proximal end

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including a longitudinal axis and a deflection mechanism (steering dial **220**) for selectively inducing a bend in the catheter body. Additionally, Nardeo discloses the deflection mechanism to contain an elongated deflection wire (control wire **50**) extending within the deflection lumen of the catheter body and into the handle, a thumb wheel (steering dial **220**) mounted within the handle and disclosed to contain a gear to control motion of the deflection wire (see col. 4; 67 - col. 5; 6) and for the rotation of the thumb wheel in a first direction to induce a first bend in the catheter body and the rotation of the thumb wheel in a second direction to induce a second bend (see col. 4; 63-66). Nardeo fails to disclose the inclusion of a guide track, the specific inclusion of a pinion gear attached to the thumb wheel, a rack arm including runners, or the various operational relations between each of the parts.

Mercereau discloses a similar steerable device containing a elongated catheter body (sheath **14**), a handle (handle **12**) and a deflection mechanism (slide assembly **18**) for articulating a portion of a catheter wherein the deflection mechanism contains a guide track (I-shaped channel **43**) formed within the handle in substantial alignment with the longitudinal axis, a thumb wheel (thumb wheel **46**) mounted proximal to the guide track and supporting a pinion gear (pinion **52**) such that the pinion gear and thumb wheel are capable of being rotated about a common thumb wheel axis perpendicular to the longitudinal axis (see figure 10). Mercereau further discloses the deflection mechanism to contain an H-shaped rack arm (gear rack **26a/26b**) including runners (ears on each rack) received by track sides formed about a distal handle segment of the guide track, an attachment point (passage **30**) coupling the deflection wire to the rack arm and a linear rack (gear teeth **29**) engaging the pinion gear and aligned parallel to the longitudinal axis wherein the rack arm is extending within the handle such that the attachment

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point, moveable about a linear path, is substantially aligned with the deflection lumen.

Mercereau further discloses the rotation of the thumb wheel in a first direction to move the linear rack proximally via the engagement of the linear rack with the pinion gear thereby moving a deflection wire proximally.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the specifics of the deflection mechanism of Mercereau in combination with the device of Nardeo to provide for a steerable catheter with bending controlled by a rack and pinion system. The inclusion of a rack and pinion system while already disclosed as capable of being used with the device of Nardeo is also well known and commonly utilized system in the art to provide deflection/bending control in catheters. Furthermore, the system of Mercereau contains the disclosed guide track and runners which ensure that the rack maintains alignment within the handle thereby effectively translating the movement of the rack to the deflection wire. While Mercereau fails to specifically disclose the oblique extension of the rack arm within the handle, such a modification/feature would be obvious to one of ordinary skill in the art in view of the above combination in order to provide the correct alignment of the rack arm/runners/guide track/attachment points with the deflection lumen in order to ensure the translation of the movement of the rack is applied to the deflection wire thereby reducing the chance of bending or kinking of the deflection wire itself.

Regarding claim 3, Nardeo discloses the handle to contain a first major side (right side surface **213**) and a second major side (left side surface **214**) and for the thumb wheel to be disposed intermediate the first and second major sides (see figure 6).

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Regarding claim 4, Nardeo discloses the handle to contain a first and second handle body portion joined along a plane substantially perpendicular to the thumb wheel axis wherein the first and second body portion capture the thumb wheel therebetween (see figures 6-8).

Regarding claims 5 and 7, Nardeo discloses the thumbwheel to contain an internal axial extension (see figures 7 and 8), a first and second sidewall joined along a longitudinal plane (side portion of steering dial **220**, see figures 6-8) and a circumferentially extending slot through the outer rim of the sidewall (see figures 7 and 8). While Nardeo fails to specifically recite the location of the pinion gear to be on the axial extension and for the rack arm to extend through the slot thereby engaging the pinion gear, it would have been obvious to one of ordinary skill in the art at the time the invention was made that in view of the combine device of the above rejected claim 1 of Nardeo in view of Mercereau, that the pinion gear would be formed on the internal axial extension and that in order for the rack arm to communicate with the deflection wire, it would extend through the slot formed in the sidewall.

Regarding claims 6 and 8, Nardeo discloses the thumbwheel to contain a first and second sidewall (side portion of steering dial **220**) and an arcuate opening through each sidewall (see figures 7 and 8). While Nardeo fails to specially recite an inwardly extending guide, it would have been obvious to one of ordinary skill in the art at the time the invention was made that in view of the combined device of the above rejected claim 1 of Nardeo in view of Mercereau, that the guide track encompassed within a guide and holding the linear rack of the rack arm against the pinion gear would extend through the slot formed in the sidewall in order to provide a secure attachment point for the deflection wire and prevent contact of the thumb wheel sidewall with the deflection wire upon rotation of the thumb wheel about its axis.

Regarding claim 9, Nardeo discloses the deflection mechanism to further contain a securing mechanism (locking device **230**) engageable in use from either the first or the second major side of the apply, the securing mechanism applying a frictional force which prevents the thumb wheel from rotating (see col. 5; 23-29).

Regarding claim 14, Nardeo discloses the handle to contain a first minor side (top surface **215**) extending between the first major side and the second major side and a first thumb wheel window (slot **218**) extending through the first minor side thereby exposing a portion of the thumb wheel (see figures 6-8).

Regarding claims 15 and 19, Nardeo discloses for the thumbwheel to include a sidewall (side portion of steering dial **220**) forming an outer rim and for the outer rim to be exposed through the first thumb wheel window (see figures 6-8).

Regarding claims 16 and 20, Nardeo discloses the outer rim to contain serrations (teeth **222**).

Regarding claims 17 and 21, Nardeo discloses the outer rim to contain an indentation (one of the plurality of indentations formed by teeth **222** exposed in the first and second wheel window).

Regarding claim 18, Nardeo discloses the handle to contain a second minor side (bottom surface **216**) opposite of the first minor side and a second thumb wheel window (slot **218**) extending through the second minor side through which a second portion of the thumb wheel is exposed (see figures 6-8).

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Regarding claims 24-26, Nardeo discloses the handle to contain a first major side (right side surface **213**) and a second major side (left side surface **214**), the first and second major sides forming a support for the thumbwheel (see figure 6) and for a grasping segment including a narrowed waist (see col. 4; 52-54) thereby facilitating ergonomic handling. Nardeo further discloses the thumbwheel to be disposed intermediate the first and second major sides (see figure 6) and for the handle to contain a first and second handle body portion joined along a plane substantially perpendicular to the thumb wheel axis wherein the first and second body portion capture the thumb wheel therebetween (see figures 6-8).

Regarding claim 27, Nardeo discloses a steerable catheter containing an elongated catheter body (catheter tubing **100**) including a proximal end, a distal segment (see figure 1) and a deflection lumen extending from the proximal end toward the distal segment (parallel lumen **15**, see figures 1 and 2) extending from the proximal end to the distal segment. Nardeo further discloses a handle (control handle **200**) coupled to the catheter body proximal end including a longitudinal axis and a deflection mechanism (steering dial **220**) for selectively inducing a bend in the catheter body. Additionally, Nardeo discloses the deflection mechanism to contain an elongated deflection wire (control wire **50**) extending within the deflection lumen of the catheter body and into the handle, a thumb wheel (steering dial **220**) mounted within the handle and disclosed to contain a gear to control motion of the deflection wire (see col. 4; 67 - col. 5; 6) and for the rotation of the thumb wheel in a first direction to induce a first bend in the catheter body and the rotation of the thumb wheel in a second direction to induce a second bend (see col. 4; 63-66). Lastly, Nardeo discloses the thumbwheel to contain an internal axial extension (see figures 7 and 8), a first and second sidewall joined along a longitudinal plane (side portion of steering dial

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220, see figures 6-8) and a circumferentially extending slot through the outer rim of the sidewall (see figures 7 and 8).). Nardeo fails to disclose the inclusion of a guide track, a rack arm including runners, the various operational relations between each of the parts and the locating of the pinion gear to be on the axial extension and for the rack arm to extend through the slot thereby engaging the pinion gear

Mercereau discloses a similar steerable device containing a elongated catheter body (sheath **14**), an inwardly extending longitudinal guide passing through an arcuate slot to interface with the linear rack and maintain its position against the pinion gear (longitudinally extending rib **58** in communication with races **42**), a handle (handle **12**) and a deflection mechanism (slide assembly **18**) for articulating a portion of a catheter wherein the deflection mechanism contains a guide track (I-shaped channel **43**) formed within the handle in substantial alignment with the longitudinal axis, a thumb wheel (thumb wheel **46**) mounted proximal to the guide track and supporting a pinion gear (pinion **52**) such that the pinion gear and thumb wheel are capable of being rotated about a common thumb wheel axis perpendicular to the longitudinal axis (see figure 10). Mercereau further discloses the deflection mechanism to contain an H-shaped rack arm (gear rack **26a/26b**) including runners (ears on each rack) received by track sides formed about a distal handle segment of the guide track, an attachment point (passage **30**) coupling the deflection wire to the rack arm and a linear rack (gear teeth **29**) engaging the pinion gear and aligned parallel to the longitudinal axis wherein the rack arm is extending within the handle such that the attachment point, moveable about a linear path, is substantially aligned with the deflection lumen. Mercereau further discloses the rotation of the thumb wheel in a first direction

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to move the linear rack proximally via the engagement of the linear rack with the pinion gear thereby moving a deflection wire proximally.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the specifics of the deflection mechanism of Mercereau in combination with the device of Nardeo to provide for a steerable catheter with bending controlled by a rack and pinion system. The inclusion of a rack and pinion system while already disclosed as capable of being used with the device of Nardeo is also well known and commonly utilized system in the art to provide deflection/bending control in catheters. Furthermore, the system of Mercereau contains the disclosed guide track and runners which ensure that the rack maintains alignment within the handle thereby effectively translating the movement of the rack to the deflection wire. While Mercereau fails to specifically disclose the oblique extension of the rack arm within the handle, such a modification/feature would be obvious to one of ordinary skill in the art in view of the above combination in order to provide the correct alignment of the rack arm/runners/guide track/attachment points with the deflection lumen in order to ensure the translation of the movement of the rack is applied to the deflection wire thereby reducing the chance of bending or kinking of the deflection wire itself. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made that in view of the combine device of Nardeo in view of Mercereau, that the pinion gear would be formed on the internal axial extension and that in order for the rack arm to communicate with the deflection wire, it would extend through the slot formed in the sidewall.

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7. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardeo et al (US Pat. No. 6,530,897 B2) in view of Mercereau et al (US Pat. No. 6,676,668 B2) as applied to claim 9 above, and further in view of Thompson et al (US Pat. No. 5,358,478).

Regarding claims 10 - 13, Nardeo discloses for the thumbwheel to include a sidewall (side portion of steering dial **220**) but neither Nardeo nor Nardeo in view of Mercereau disclose the inclusion of a resilient compressible member to be disposed in a gap between the sidewall and either the first or second major side of the handle body.

Thompson discloses a steerable catheter (catheter **10**) containing a thumb wheel (steering mechanism **18**, steering lever **34**), a deflection wire (wire **58**) and a deflection mechanism including a securing mechanism (locking lever **38**, see figure 1) selectively engageable to apply a frictional force to the thumb wheel (see col. 4; 10-24). Thompson further discloses the securing mechanism to consist of a resilient compressible member (o-ring, see col. 4; 13-14) disposed in the gap between the thumb wheel sidewall and one of the first major side and the second major side of the handle body. Additionally, Thompson discloses that one of the first or second major sides of the handle includes a window and a thumb slide extending therethrough (locking lever **38**, see figure 1) such that the thumb slide adapted to apply a lateral force pushing the thumb wheel against the resilient compressible member thereby engaging the securing mechanism (see col. 4; 10-24) wherein the securing mechanism further includes an elongated ring (screw **24**, threaded washer **26**) coupled to the thumb slide whereby the thumb slide applies the lateral force by wedging the elongated ring between the thumb wheel and one of the first major side and the second major side (see col. 4; 10-24) and wherein the securing mechanism further includes a means to adjust the gap between the thumb wheel sidewall and the one of the first major side and

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the second major side of the handle body (via increasing the seating force on the cam, see col. 4; 10-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the locking mechanism of Thompson in combination with the combined catheter of Nardeo in view of Mercereau as disclosed above in order to prevent rotation of the wheel thereby effectively locking the catheter in a set position when a desired placement/orientation has been reached. It is further noted that applicant's specification fails to attribute any significance (novel or unexpected results) in reference to this particular arrangement and as such, this particular arrangement is deemed to have been a design consideration within the skill of one in the art. In re Kuhle, 526 F.2d 553,555, 188 USPQ 7, 9 (CCPA 1975). Furthermore, applicant has not disclosed that the specific disclosed securing mechanism is used for a particular reason or solves a specific problem and as such, it would have been an obvious matter of design choice to modify the device of Nardeo in view of Mercereau to obtain the disclosed invention of claims 10 – 13.

Response to Arguments

8. Applicant's arguments, see the remarks, filed June 18th, 2008, with respect to the rejection(s) of claim(s) 1-27 under 35 U.S.C 103(a) have been fully considered and are persuasive. The examiner notes the combination of Nardeo in view of Lowe, as pointed out by applicant, fails to disclose alone or in combination, each of the structural pieces of independent claims 1 and 27. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Nardeo (US Pat. No. 6,530,897 B2) in view of Mercereau (6,676,668 B2) and/or Thompson (5,358,478).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD J. HUPCZEY, JR. whose telephone number is (571)270-5534. The examiner can normally be reached on Mon. - Fri. from 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD J HUPCZEY, JR./
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH